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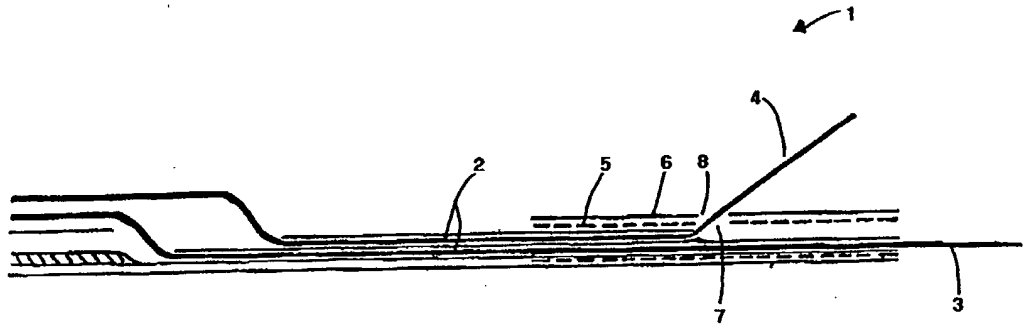

(57) Abstract

This invention relates to self–expanding bifurcation stents, a delivery sleeve for such stents and a method of delivery of such stents. The invention is designed to improve the accuracy and effectiveness of deployment of self–expanding stents at a bifurcation. The system (1) includes a self–expanding stent (5) and corresponding delivery sleeve (6) adapted to house two guidewires (3, 4), one of which exits from the distal end and a second of which exits from a side hole (8) in the stent (5). In a preferred form, the side hole (8) in the delivery sleeve (6) extends from the position of exit of the second guidewire (4) through the stent (5) to the distal end of the sleeve. Means are provided for ensuring that the slotted delivery sleeve effectively confines the self–expanding stent (5) until it needs to be deployed.

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SELF-EXPANDING BIFURCATION STENT AND DELIVERY SYSTEM

TECHNICAL FIELD OF THE INVENTION

This invention relates to a system and apparatus for treating vascular disease, and in particular to a design of self-expanding stent delivery sleeve and self-expanding stent, and to a method of deployment of self-expanding stents in a bifurcation lesion. The system and apparatus could also be applied to bifurcation lesions in non-vascular structures, such as the gastro intestinal tract.

BACKGROUND TO THE INVENTION

Vascular disease commonly involves the development of stenotic lesions in the vasculature. Such lesions commonly occur at bifurcations, where a parent vessel divides into two branch vessels. Bifurcation lesions remain difficult to treat, but a common form of treatment is the use of vascular stents.

There are two main categories of stents: balloon-expandable stents and self-expanding stents. International Patent Application No. PCT/US98/03553 (International Publication No. WO 98/36709) describes a stent and stent delivery system involving balloon-expandable stents, used in the management of bifurcation lesions. That patent specification describes the problems associated with treating or managing bifurcation lesions.

Self-expanding stents are another type of stent used to treat coronary and peripheral vascular lesions including those in the carotid, renal and aorto-iliac vessels. They are particularly suited to the treatment of stenotic lesions in the carotid vessels, which frequently involve the bifurcation of the common with the internal and external carotid. Balloon-

expandable stents are usually made of stainless steel and are reasonably rigid in expanded form. This makes them of particular value in the treatment of coronary vessels. Self-expanding stents are often made of stainless steel or of nitinol. Nitinol resists compression and returns to its previous shape following transient compression. Nitinol self-expanding stents are particularly suited to carotid lesions, where the stent may be distorted by neck movement.

The patent specification accompanying PCT/US98/03553 describes a system whereby separate guidewires may be positioned in each of the branch vessels of a bifurcation. A first balloon-expandable stent, mounted on its delivery balloon and advanced over both the first guidewire and the second guidewire which exits from a hole in a mid-side portion of the stent and its balloon, is advanced in to the first branch vessel at the region of the bifurcation, and deployed. A second stent may then be advanced along the second guidewire through the hole in the first stent (located at the ostium to the second branch) and positioned in the second branch at the region of the bifurcation. With this balloon-expandable system, both stents may be accurately positioned and fixed in place by expansion of the balloon without the need to move either guidewire.

A problem arises with self-expanding stents in that such stents are retained in their constrained form by a sheath or sleeve which must be withdrawn or rolled back to enable the stent to expand. The stent cannot be secured in a preferred position in a blood vessel until at least a part of it is in its expanded form. The sleeves of conventional self-expanding stents do not include a hole adapted to enable a second guidewire to exit to the second branch of a bifurcation, and even if they did it would not be possible (with such conventional sleeves) to retain the second guidewire in place whilst the sleeve is withdrawn to secure the position of the distal end of the first stent.

Thus, it is an object of the present invention to provide a self-expanding stent, a delivery system for such stents and a method of delivery of self-expanding stents which reduces or overcomes the abovementioned problems, or which at least provide the public with a useful alternative.

Other objects of the invention may become apparent from the following description which is given by way of example only.

SUMMARY OF THE INVENTION

According to one aspect of the present invention there is provided a stent delivery sleeve adapted for the delivery of a self-expanding stent at a bifurcation in a parent vessel, the bifurcation bifurcating the parent vessel into first and second branch vessels, and the sleeve adapted to constrain the self-expanding stent in restricted form and enable expansion of the stent by withdrawal of the sleeve, the stent delivery sleeve including a substantially tubular vessel having a first outlet at a distal end and a second outlet through a side portion of the tubular vessel at a distance sufficiently remote from the distal end to enable a distal portion of the tubular vessel, in use of the stent delivery sleeve, to be located within the first branch vessel whilst the second outlet is located at the ostium to the second branch vessel and a proximal portion of the tubular vessel is disposed in the parent vessel.

According to a second aspect of the invention there is provided a stent delivery system adapted for the delivery of a self-expanding stent at a bifurcation, the bifurcation bifurcating a parent vessel into first and second branch vessels, the stent delivery system adapted, at least in a proximal portion, to accommodate at least two guidewires, and including:

- a stent delivery sleeve adapted to constrain a self-expanding stent in restricted form and enable expansion of the stent by withdrawal of the sleeve, and including a substantially tubular vessel having a first outlet at a distal

end and a second outlet through a side portion of the tubular vessel at a distance sufficiently remote from the distal end to enable a distal portion of the tubular vessel, in use of the stent delivery sleeve, to be located within the first branch vessel whilst the second outlet is located at the ostium to the second branch vessel and a proximal portion of the tubular vessel is disposed in the parent vessel; and

- a self-expanding stent constrained within at least the distal portion of the stent delivery sleeve;

According to a third aspect of the invention there is provided a self-expanding stent for deployment at a lesion site in a bifurcation, the stent including a distal end, proximal end, a longitudinal length therebetween sufficient for a distal portion to be disposed in a first branch vessel of the bifurcation whilst a proximal portion is disposed in the parent vessel, and a lateral hole in the longitudinal length, said hole adapted to accommodate at least a guidewire when the stent is in a constrained form.

According to a further aspect of the invention there is provided a self-expanding stent for deployment at a lesion site in a bifurcation, the stent including a distal end, a proximal end and a longitudinal length therebetween, the proximal end forming an angle in relation to the longitudinal length, such that the stent has a longer longitudinal side and a shorter longitudinal side.

According to a further aspect of the invention there is provided a method of deploying one or more self-expanding stents at stenotic lesions in a bifurcation, the bifurcation involving the division of a parent vessel into first and second branch vessels, the method including:

- advancing a first guidewire through the parent vessel into the first branch vessel;

- advancing a second guidewire through the parent vessel into the second branch vessel;

- advancing a main stent delivery sleeve housing a first self-expanding stent along the guidewires, the first guidewire exiting at a first outlet at the distal end of the stent delivery sleeve and the second guidewire exiting at a second outlet in a side portion of the stent delivery sleeve and comprising a slot which extends to the distal end of the main stent delivery sleeve, until a distal portion of the stent delivery sleeve is disposed in the first branch vessel, a proximal portion is disposed in the parent vessel and the second outlet is disposed adjacent the ostium of the second branch vessel;

- withdrawing the main stent delivery sleeve to deploy the first self-expanding stent, the second guidewire maintained in position in the second branch vessel and exiting the delivery sleeve along the slot.

In an alternative method the second outlet may be an elongate hole or slot not extending to the distal end of the stent delivery sleeve, such that the method further includes partial withdrawal of the stent delivery sleeve to deploy a distal end of the first self-expanding stent only and withdrawal of the second guidewire into the stent delivery sleeve before complete withdrawal of the sleeve to fully deploy the first stent.

Further aspects of the invention may become apparent from the following description which is given by way of example only and with reference to the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1: shows a longitudinal section through a stent and stent delivery sleeve of the present invention, in one preferred form;

Figure 2: shows a perspective view of a stent delivery sleeve of the invention in one preferred form;

Figure 3: shows a cross section through a distal end of a stent and stent delivery sleeve of Figure 2;

Figure 4: shows a perspective view of a stent delivery sleeve of the invention in an alternative embodiment;

Figure 5: shows a perspective view of a stent delivery sleeve of the invention in a further embodiment;

Figure 6: shows a schematic representation of a stent delivery system of the present invention employing a monorail design;

Figure 7: shows a perspective view of a stent and stent delivery sleeve of the invention in a further embodiment;

Figure 8: shows an enlarged schematic representation of the zip-type system of the stent delivery sleeve of Figure 8;

Figure 9: shows a longitudinal section through an angled self-expanding stent and stent delivery sleeve of the invention.

DETAILED DESCRIPTION OF THE INVENTION

A conventional self-expanding stent and delivery system includes a single central guidewire lumen, which at the proximal end may include a monorail or over-the-wire configuration, and has the stent securely constrained towards the distal end by a retractable sleeve.

In contrast, with reference to Figure 1, a self-expanding stent delivery system 1 of the present invention has two rather than one central guidewire lumen 2, housing two separate guidewires 3, 4. One guidewire 3 exits from the distal end 4 of the delivery system 1, in the normal manner. The second guidewire 4 exits from a hole 7 in the side of the stent 5 and a hole 8 in the stent delivery sleeve 6.

Whilst the system of Figure 1 involves a monorail configuration, it will be appreciated by those skilled in the art that the delivery system of the present invention could equally be employed with an over-the-wire configuration, or a combination of the two.

The stents employed with the delivery system of the present invention are modifications of known self-expanding stents. The key modification being the requirement for a gap or hole in the stent at a point in its side, and through which a guidewire and stent delivery system may pass. This gap or hole must be sufficiently large when the stent is in its constrained configuration to allow the passage of a guidewire, and in a preferred form (as described below) it must be sufficiently large to accommodate a guidewire within a guidewire tube.

The hole in the stent, when it is expanded, is substantially the diameter of the ostium of a branch vessel. The proximal and distal portions of the stent may have the same nominal expanded diameter or the proximal portion may be larger or smaller in nominal expanded diameter than the distal portion. For example, the proximal portion may be 0.5mm larger (coronary design) or 1mm larger (carotid design) in diameter than the distal portion, or the proximal portion may be 1 to 2mm

smaller (aorto-iliac design) in diameter than the distal portion. One or more extra joins connecting zig zag segments of a stent may be necessary to add stability and support to the stent in the segments immediately opposite and adjacent the side hole.

The stent delivery system of the invention is broadly designed to enable deployment of one or more self-expanding stents at a bifurcation.

In its simplest form, as shown in Figures 4 and 6, the stent delivery sleeve 14 includes a hole 10 through which the second guidewire 4 exits. It will be appreciated that with this simple version, in order to deploy a first self-expanding stent, substantially in the position shown in Figure 6, (with the stent overlapping the parent vessel 11 and first branch vessel 12), it is necessary to retract the second guidewire 4 into the sleeve and then to retract the sleeve 14 to enable the self-expanding stent to expand. The second guidewire 4 may then be advanced back through the hole 10 again and back into the second branch vessel 13 of the bifurcation to enable the deployment of a second stent, if necessary, in that second branch.

The need to withdraw the second guidewire 4 into the sleeve 14 with the embodiment of sleeve shown in Figures 4 and 6 is an important limitation since any movement of the delivery system after guidewire withdrawal may adversely affect the accuracy of deployment of stents; especially the orientation of the holes 7, 10 may shift in relation to the ostium of the second branch vessel.

The embodiment of Figure 5 is adapted to reduce this problem. In this embodiment the hole in the stent delivery sleeve 22 is replaced with a longitudinal or oval slot 20. This slot is positioned adjacent to the hole 21 in the stent, and extending distally of that hole. The rim of the slot may require reinforcing to adequately constrain the stent prior to deployment. With this embodiment the stent delivery sleeve 22 may be withdrawn a small amount (the extent of the slot) to deploy and anchor

the distal end of the first stent, before it is necessary to retract the second guidewire 4.

The method of deployment of one or more self-expanding stents using the sleeve 22 of Figure 5 is as follows. The first stent in its stent delivery sleeve is advanced over two guidewires as before. When in position (as per Figure 6), the sleeve is withdrawn a sufficient amount (about 1cm) to deploy the distal end of the stent. This anchors the stent in position. Only then is the second guidewire withdrawn into the shaft of the delivery system so that the first stent may be fully deployed. If a second stent is required in the second branch, the guidewire is then readvanced through the hole in the stent and along the second branch, and a second stent is advanced along that second guidewire for positioning in the second branch, as before. It will be appreciated that with this system the risk of inadvertently moving the first stent out of position, and thus misaligning the hole in the stent with the ostium of the second branch, is reduced.

The embodiments of Figures 2, 3, 7 and 8 are the preferred embodiments of the stent delivery sleeve of the invention. In each of these embodiments the hole in the stent delivery sleeve 32 is a slot 30 which extends right through to the distal end 31 of the sleeve 32. The guidewire lumen 44 through which guidewire 4 exits may end distally inside the stent, may extend through the stent but not the delivery sleeve, may extend a few mm beyond the delivery sleeve, or may extend further into the second branch vessel 13. It will be appreciated that the guidewire lumen 44 in combination with the proximal end of the slot can be important in positioning of the stent delivery system at a bifurcation.

To maintain the shape of the delivery sleeve 32 before and during deployment, the sleeve 32 requires additional strengthening, in either a circumferentional or longitudinal direction, or both, at least in the portion of sleeve in the region of the slot 30. This strengthening may be in the form of one or more reinforcing ribs or bands 33 of metal, plastic or other strengthening material. In the embodiment of Figure 2 the strengthening

is shown as a series of bands 33 extending around most of the circumference of the sleeve 32. There are also longitudinal ribs 34, at least adjacent the edges 35 of the slot 30. If both longitudinal and circumferential reinforcing is employed, the longitudinal ribs 34 may or may not wholly or in part be attached to the circumferential bands 33.

In the embodiment of Figure 7 the requirement for strengthening of the stent delivery sleeve is avoided by including a zip-type system in the slot. Thus, the longitudinal slot 40 in the stent delivery sleeve 41 is joined at one or more sites 42. Each join 42 is adapted to separate as the delivery sleeve 41 is withdrawn. As the sleeve 41 is withdrawn the guidewire 4 extending through the side of the stent 43 and the delivery sleeve 41, or the guidewire 4 and the tube 44 through which it runs (and which may also extend out of the delivery sleeve), acts as the release mechanism to separate each join 42 in turn. This is shown schematically in Figure 8.

It will be appreciated that as the "zip" is undone, there will be a portion of the self-expanding stent 43 proximal of the hole 45 in the stent 43, which is not constrained by the sleeve. In order to avoid inappropriate deployment of this portion of the stent 43, the delivery system may include an additional sleeve 46 about the stent 43 in the proximal portion 47 of the delivery sleeve 41 up to the position of exit of the second guidewire 4. Once the delivery sleeve 41 has been withdrawn either completely or to the position of the additional sleeve 46, then sleeve 46 is withdrawn either alone or with sleeve 41 to fully deploy the stent.

This additional sleeve 46 could alternatively be positioned externally of the delivery sleeve 41, in the same proximal portion 47.

It will be appreciated that the particular zip-configuration shown in Figures 7 and 8 is only one example of the manner in which two edges of a slotted sleeve may be interconnected. Those skilled in the relevant art will be aware of other designs of joining sufficiently secure to restrain

a self-expanding stent, but releasable under a given pressure, preferably in one direction only.

Stent deployment in the second branch vessel 13 may be with a known self-expanding type or a balloon-inflatable type stent and it may be advanced over the single second guidewire 4. However, the angle between first branch vessel 12 and second branch vessel 13 is often much less then 90°. In such circumstances a stent with an angled proximal end may provide optimal coverage of the second branch vessel 13 ostium. The angled stent may be a modification of current designs with removal of zig zag segments from part of the stent's circumference at its proximal end. The remaining segments at that end may need additional joins to maintain stent integrity following deployment. The delivery system to optimally align this stent is depicted in Figure 9. It is similar to the delivery systems to deploy the side hole self-expanding stent depicted in Figures 1 - 8, except that the hole or proximal end of the slot 56 through which guidewire 58 in the first branch vessel passes is proximal to the stent, or at least the shorter longitudinal side of the stent. Deployment of such an angled stent is described below.

Alternatively, a stent and delivery sleeve of similar design to that of the first stent and delivery sleeve may be used, but with the second guidewire 4 exiting distally and the first guidewire 3 exiting from the hole 10 in the side.

The manner in which two stents can be configured to provide optimum protection at a bifurcation is described in PCT/US98/03553 (as referred to above), although it will be appreciated that the actual stents and delivery mechanism in that patent, which relates to balloon-inflated stents, is different from that required for the self-expanding stents employed with the present invention.

The method of use of a self-expanding bifurcation stent and delivery sleeve of the embodiment of Figure 7 will now be described.

First 3 and second 4 guidewires are advanced along the blood vessel to the bifurcation, at which point one guidewire is fed along each branch of the bifurcation. One or both branch vessels may be dilated with regular angioplasty balloons to increase the vessel lumen and aid positioning of the stent and delivery system. With the guidewires in place the stent and delivery system is fed along both wires until the distal end is located in the first branch and the point of exit of the second guidewire through the side of the stent and delivery sleeve is adjacent the ostium of the second branch. With the additional sleeve 46 maintained adjacent the exit of the second guidewire 4 from the delivery sleeve 41, the delivery sleeve is gradually withdrawn, causing the zip system to undo through contact with the guidewire 4, or preferably the guidewire tube 44. Once the distal end of the delivery sleeve reaches the additional sleeve, then both sleeves are withdrawn together to deploy the remainder of the first stent in the parent vessel. If a second stent is required in the second branch vessel this may be achieved by advancement of a second stent deployment unit along both guidewires or just the second guidewire, as previously described.

Angled self-expanding stents have not previously been used. The reason for this is primarily because of the difficulty in accurately deploying such a stent in the right orientation. This can be overcome using a stent delivery sleeve and system of the present invention. Thus, after deployment of a first self-expanding stent, as described above, a second delivery system (as, for example, shown in Figure 9) is introduced. It should be appreciated an angled self-expanding stent may be delivered into one branch unit using a delivery system of the invention prior to the delivery of a stent with a side hole into the other branch and parent vessel.

With reference to Figure 9, in this second delivery system 50 the self-expanding stent 51 is located within the distal portion 52 of the stent delivery sleeve 53, with the proximal end 54 of the shorter longitudinal side 55 of the stent 51 adjacent the hole or proximal end of the slot 56. A proximal portion 59 of the sleeve 53 may be shorter than the equivalent

portion of the other embodiments of delivery system described above. The guidewires are in the reversed configuration of that in the first stent delivery system, i.e. second guidewire 57 passes directly through the stent and sleeve, whilst the first guidewire 58 exits through the hole or slot in the sleeve proximal to the stent 51. The second delivery system is then fed along the guidewires, with the distal end guided into the second branch vessel along the second guidewire, until the hole or proximal end of the slot in the sleeve is located over the ostium of the first branch vessel. The angled self-expanding stent will then be correctly oriented and optimally positioned within the second branch vessel. It can be deployed in the same manner as the first self-expanding stent, i.e. as described above for the three different types of delivery sleeve with a hole, short longitudinal slot or full slot extending to the distal end of the sleeve.

Whilst there would be some reduction in the accuracy of deployment of an angled self-expanding stent if the delivery system had a sleeve with no lateral hole or slot, but rather the guidewire 58 exited proximal of the sleeve 53, it would, nonetheless, be possible to deploy an angled stent with such a delivery system. The positioning of the outlet 60 of the first guidewire lumen 61 would be critical in such a delivery system configuration, since it would be this position which determined the positioning of the system in the bifurcation at the time of deployment of the stent.

The advantage of the slotted stent delivery sleeve is that the guidewires positioned in both branches of the bifurcation are maintained throughout the deployment procedure. Thus, the risk of inadvertent movement of the first stent out of position during deployment is minimised.

Where in the foregoing description reference has been made to specific components or integers of the invention having known equivalents then such equivalents are herein incorporated as if individually set forth.

Although this invention has been described by way of example and with reference to possible embodiments thereof it is to be understood that modifications or improvements may be made thereto without departing from the scope or spirit of the invention.

CLAIMS:

1. A stent delivery sleeve adapted for the delivery of a self-expanding stent at a bifurcation in a parent vessel, the bifurcation bifurcating the parent vessel into first and second branch vessels, and the sleeve adapted to constrain the self-expanding stent in restricted form and enable expansion of the stent by withdrawal of the sleeve, the stent delivery sleeve including a substantially tubular vessel having a first outlet at a distal end and a second outlet through a side portion of the tubular vessel at a distance sufficiently remote from the distal end to enable a distal portion of the tubular vessel, in use of the stent delivery sleeve, to be located within the first branch vessel whilst the second outlet is located at the ostium to the second branch vessel and a proximal portion of the tubular vessel is disposed in the parent vessel.

2. A stent delivery sleeve according to claim 1 wherein the second outlet extends distally along the stent delivery sleeve.

3. A stent delivery sleeve according to claim 1 wherein the second outlet is in the form of a longitudinal slot extending to the distal end of the substantially tubular vessel.

4. A stent delivery sleeve according to claim 3 wherein the distal portion of the substantially tubular vessel in the region of the slot, includes strengthening means.

5. A stent delivery sleeve according to claim 4 wherein the strengthening means includes one or more spaced-apart circumferential rib members.

6. A stent delivery sleeve according to either claim 4 or claim 5 wherein the strengthening means includes one or more spaced-apart longitudinal rib members.

7. A stent delivery sleeve according to any one of claims 3 to 6 further including releasable slot closure means adapted to secure longitudinal edges of the slot together.

8. A stent delivery sleeve according to claim 7 wherein the releasable slot closure means includes one or more pairs of inter-engageable members on the longitudinal edges of the slot.

9. A stent delivery sleeve according to claim 8 wherein the or each pair of inter-engageable members are separable by a force applied to their proximal end to release their distal end, to open the slot from the proximal to the distal end.

10. A stent delivery sleeve according to any one of claims 1 to 9 adapted for use with a monorail delivery system.

11. A stent delivery sleeve according to any one of claims 1 to 9 adapted for use with an over-the-wire delivery system.

12. A stent delivery sleeve according to any one of claims 1 to 9 adapted for use with a combination monorail/over-the-wire system.

13. A stent delivery system adapted for the delivery of a self-expanding stent at a bifurcation, the bifurcation bifurcating a parent vessel into first and second branch vessels, the stent delivery system adapted, at least in a proximal portion, to accommodate at least two guidewires, and including:

- a stent delivery sleeve adapted to constrain a self-expanding stent in restricted form and enable expansion of the stent by withdrawal of the sleeve, and including a substantially tubular vessel having a first outlet at a distal end and a second outlet through a side portion of the

tubular vessel at a distance sufficiently remote from the distal end to enable a distal portion of the tubular vessel, in use of the stent delivery sleeve, to be located within the first branch vessel whilst the second outlet is located at the ostium to the second branch vessel and a proximal portion of the tubular vessel is disposed in the parent vessel; and

- a self-expanding stent constrained within at least the distal portion of the stent delivery sleeve.

14. A stent delivery system according to claim 13 wherein the self-expanding stent has an angled proximal end, such that it has a shorter longtudinal side and a longer longitudinal side, and wherein the proximal end of the shorter longitudinal side is located within the stent delivery sleeve adjacent the second outlet.

15. A stent delivery system according to claim 13 wherein the self-expanding stent has a lateral hole positioned adjacent the second outlet of the stent delivery sleeve, and the self-expanding stent extends proximally of the second outlet, within the stent delivery sleeve.

16. A stent delivery system according to any one of claims 13 to 15 wherein the second outlet extends distally along the stent delivery sleeve.

17. A stent delivery system according to any one of claims 13 to 15 wherein the second outlet comprises a longitudinal slot in the stent delivery sleeve extending to the distal end of the sleeve.

18. A stent delivery system according to claim 17 wherein the stent delivery sleeve includes strengthening means in the region of the slot.

19. A stent delivery system according to claim 18 wherein the strengthening means includes one or more spaced-apart circumferential rib members.

20. A stent delivery system according to either claim 18 or claim 19 wherein the strengthening means includes one or more spaced-apart longitudinal rib members.

21. A stent delivery system according to any one of claims 17 to 20 wherein the stent delivery sleeve further includes releasable slot closure means adapted to secure longitudinal edges of the slot together.

22. A stent delivery system according to claim 21 wherein the releasable slot closure means includes one or more pairs of inter-engageable members on the longitudinal edges of the slot.

23. A stent delivery system according to claim 22 wherein the or each pair of inter-engageable members are separable by a force applied to their proximal end to release their distal end, to open the slot from the proximal to the distal end.

24. A stent delivery system according to any one of claims 17 - 23 further including supplementary stent retention means adapted to retain the self-expanding stent in its constrained configuration proximal of the second outlet of the substantially tubular vessel when the slot closure means is/are released.

25. A stent delivery system according to claim 24 wherein the supplementary stent retention means comprises an additional sleeve proximal of the slot.

26. A stent delivery system according to claim any one of claims 13 to 25 further including first and second guidewires, the first guidewire extending through the self-expanding stent and exiting

through the first outlet of the stent delivery sleeve and the second guidewire passing through the proximal portion of the self-expanding stent and exiting through the second outlet of the stent delivery sleeve.

27. A stent delivery system according to claim 26 further including a guidewire tube for each guidewire, said guidewire tubes providing passageways for the guidewires at least through the stent delivery sleeve.

28. A stent delivery system according to claim 27 wherein the guidewire tube for the second guidewire extends through the second outlet.

29. A stent delivery system according to any one of claims 13 to 28 further including a second stent deployment unit positioned about at least the second guidewire proximal to the stent delivery sleeve.

30. A stent delivery system according to claim 29 wherein the second stent deployment unit deploys a second self-expanding stent.

31. A stent delivery system according to claim 30 wherein the second stent deployment unit is a second stent delivery system but arranged with the second guidewire exiting from its first outlet and the first guidewire exiting from its second outlet.

32. A stent delivery system according to claim 29 wherein the second stent deployment unit deploys a balloon-inflated stent.

33. A self-expanding stent for deployment at a lesion site in a bifurcation, the stent including a distal end, a proximal end, a longitudinal length therebetween sufficient for a distal portion to be disposed in a first branch vessel of the bifurcation whilst a

proximal portion is disposed in the parent vessel, and a lateral hole in the longitudinal length, said hole adapted to accommodate at least a guidewire when the stent is in a constrained form.

34. A self-expanding stent according to claim 33 wherein the lateral hole is adapted when the stent in its constrained form, to accommodate a guidewire housed within a guidewire tube.

35. A self-expanding stent according to either claim 33 or claim 34 wherein the lateral hole has a diameter, when the stent is in its expanded form, substantially corresponding to that of an ostium of a branch vessel at a bifurcation.

36. A self-expanding stent for deployment at a lesion site in a bifurcation, the stent including a distal end, a proximal end and a longitudinal length therebetween, the proximal end forming an angle in relation to the longitudinal length, such that the stent has a longer longitudinal side and a shorter longitudinal side.

37. A method of deploying one or more self-expanding stents at stenotic lesions in a bifurcation, the bifurcation comprising a parent vessel which divides into first and second branch vessels, the method including the steps of:

- advancing a first guidewire through the parent vessel into the first branch vessel;

- advancing a second guidewire through the parent vessel into the second branch vessel;

- advancing a main stent delivery sleeve, housing a first self-expanding stent, along the guidewires, the first guidewire exiting at a first outlet at the distal end of the stent delivery sleeve and the second guidewire exiting at a second outlet in a side portion of the stent delivery

sleeve, the second outlet extending distally, until a distal portion of the stent delivery sleeve is disposed in the first branch vessel, a proximal portion of the stent delivery sleeve is disposed in the parent vessel and the second outlet is disposed adjacent the ostium of the second branch vessel;

- at least partially withdrawing the stent delivery sleeve to deploy at least a distal end of the first self-expanding stent in the first branch vessel whilst maintaining the second guidewire in the second branch vessel;

- withdrawing the second guidewire into the stent delivery sleeve; and

- withdrawing the stent delivery sleeve to fully deploy the first self-expanding stent.

38. A method of deploying one or more self-expanding stent at stenotic lesions in a bifurcation, the bifurcation involving the division of a parent vessel into first and second branch vessels, the method including:

- advancing a first guidewire through the parent vessel into the first branch vessel;

- advancing a second guidewire through the parent vessel into the second branch vessel;

- advancing a main stent delivery sleeve housing a first self-expanding stent along the guidewires, the first guidewire exiting at a first outlet at the distal end of the stent delivery sleeve and the second guidewire exiting at a second outlet in a side portion of the stent delivery sleeve and comprising a slot which extends to the distal

end of the main stent delivery sleeve, until a distal portion of the stent delivery sleeve is disposed in the first branch vessel, a proximal portion is disposed in the parent vessel and the second outlet is disposed adjacent the ostium of the second branch vessel;

- withdrawing the main stent delivery sleeve to deploy the first self-expanding stent, the second guidewire maintained in position in the second branch vessel and exiting the delivery sleeve along the slot.

39. The method of claim 38 further including the step of preventing early deployment of a proximal portion of the first self-expanding stent during withdrawal of the slotted stent delivery sleeve.

40. The method of any one of claims 37 - 39 wherein the first self-expanding stent includes a distal end, a proximal end, a longitudinal length therebetween sufficient for a distal portion to be disposed in a first branch vessel of the bifurcation whilst the proximal portion is disposed in the parent vessel, and a lateral hole in the longitudinal length, said lateral hole aligned with a proximal part of the second outlet such that the second guidewire exits through said lateral hole and second outlet.

41. The method of claim 40 further including the step of advancing a second stent deployment unit over at least the second guidewire through a proximal end of the deployed first stent and through the lateral hole in the first stent to the second branch vessel, and deploying the second stent in the second branch vessel.

42. The method of claim 41 wherein the second stent deployment unit includes a second stent delivery sleeve housing a second self-expanding stent, each of substantially the same configuration as the main stent delivery sleeve and first self-expanding stent, respectively, except that the second guidewire exits through the

first outlet of the second stent delivery sleeve and the first guidewire exits through its second outlet.

43. The method of claim 41 wherein the second stent deployment unit includes a second stent delivery sleeve of substantially the same configuration as the main stent delivery sleeve, housing a self-expanding stent having a distal end, a proximal end and a longitudinal length therebetween, the proximal end forming an angle in relation to the longitudinal length such that the stent has a longer longitudinal side and a shorter longitudinal side, a proximal end of said shorter longitudinal side located adjacent a proximal part of the second outlet, and with the second guidewire exiting through the first outlet of the second stent delivery sleeve and the first guidewire through the second outlet.

44. A stent delivery system adapted for the delivery of a self-expanding stent at a bifurcation, the bifurcation bifurcating a parent vessel into first and second branch vessels, the stent delivery system adapted, at least in a proximal portion, to accommodate at least two guidewires, and including:

- a stent delivery sleeve adapted to constrain a self-expanding stent in restricted form and enable expansion of the stent by withdrawal of the sleeve;

- a first guidewire lumen extending through the stent delivery sleeve to a distal end of that sleeve;

- a second guidewire lumen terminating just proximal of a proximal end of the stent delivery sleeve, the distance between the distal end of the stent delivery sleeve and the terminal end of the second guidewire lumen sufficient to enable a distal portion of the stent delivery sleeve, in use of the stent delivery sleeve, to be located within the first branch vessel whilst the terminal end of the second

guidewire lumen is located at the ostium to the second branch vessel; and

- a self-expanding stent constrained within the distal portion of the stent delivery sleeve.

45. A stent delivery sleeve for a self-expanding stent substantially as herein described with the reference to the accompanying drawings.

46. A stent delivery system substantially as herein described and with reference to the accompanying drawings.

47. A self-expanding stent substantially as herein described and with reference to the accompanying drawings.

48. A method of deploying self-expanding stents at a bifurcation, substantially as herein described with reference to the accompanying drawings.

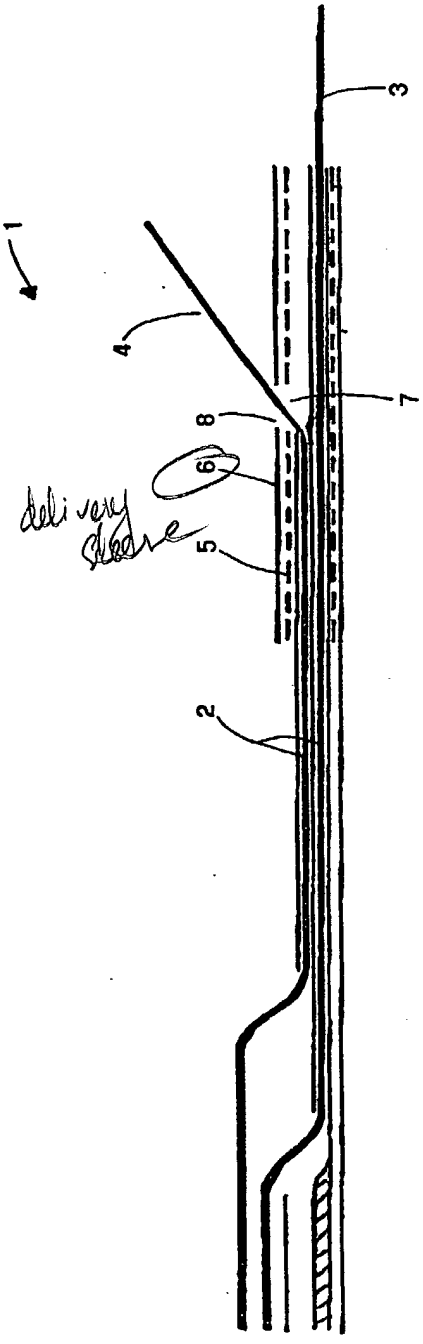

FIGURE 1

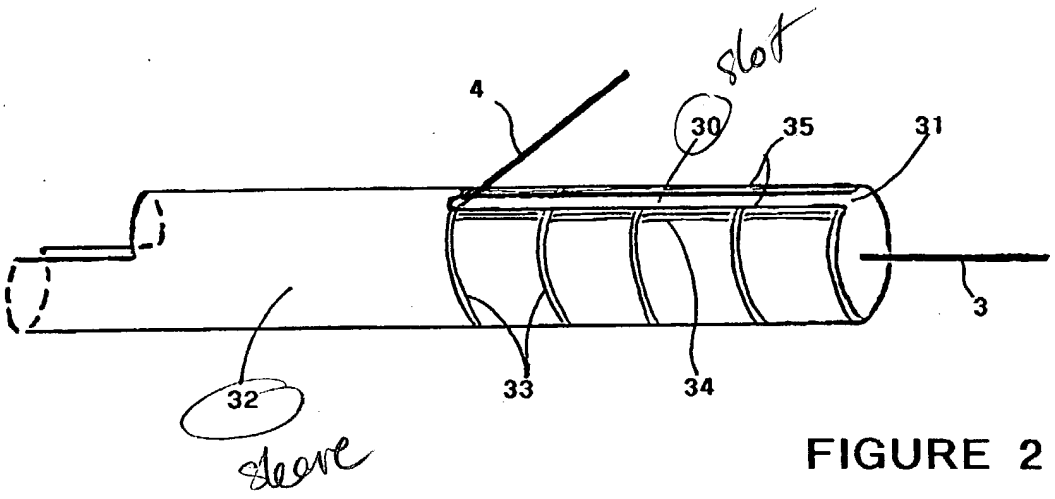

FIGURE 2

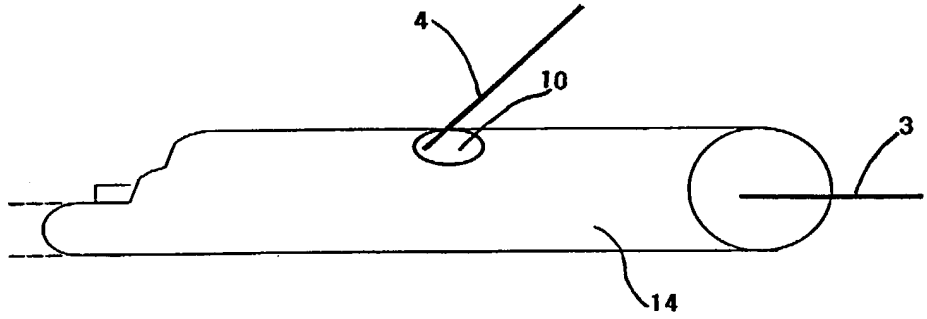

FIGURE 4

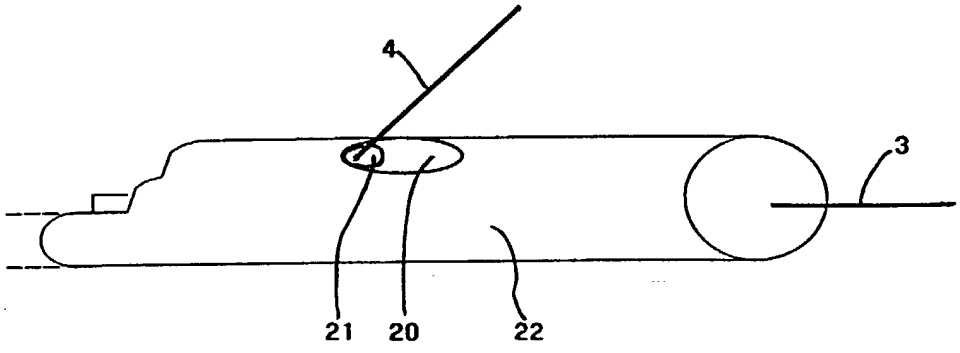

FIGURE 5

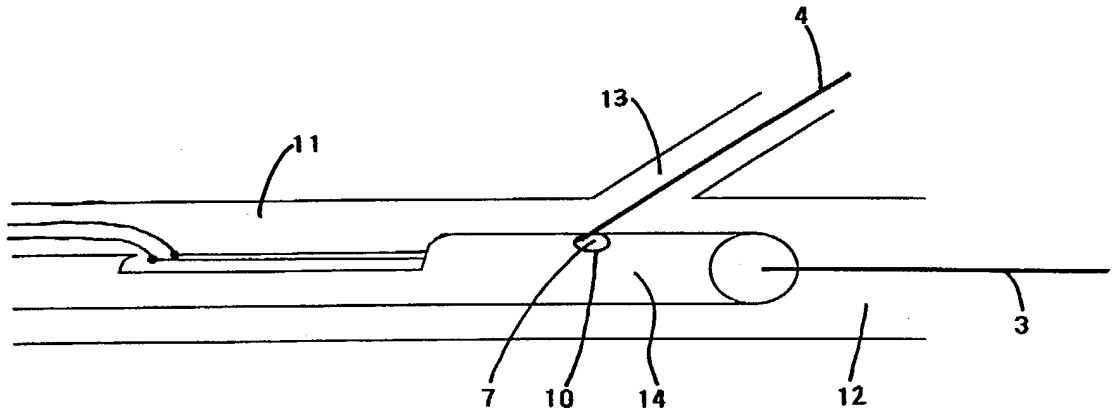

FIGURE 6

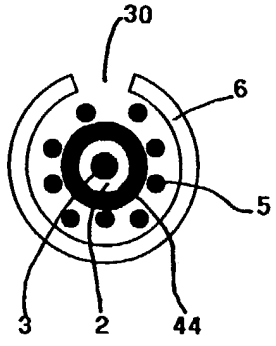

FIGURE 3

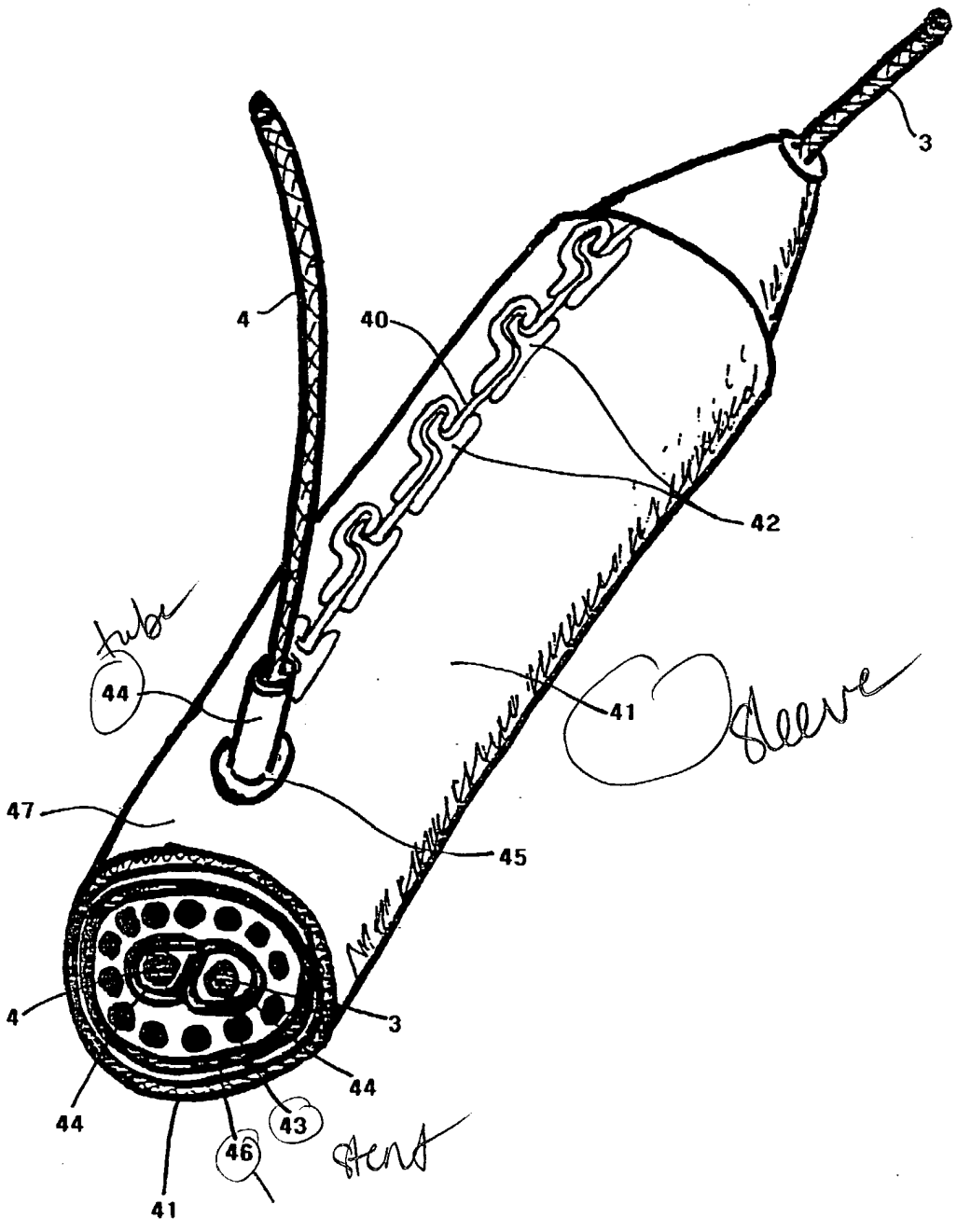

FIGURE 7

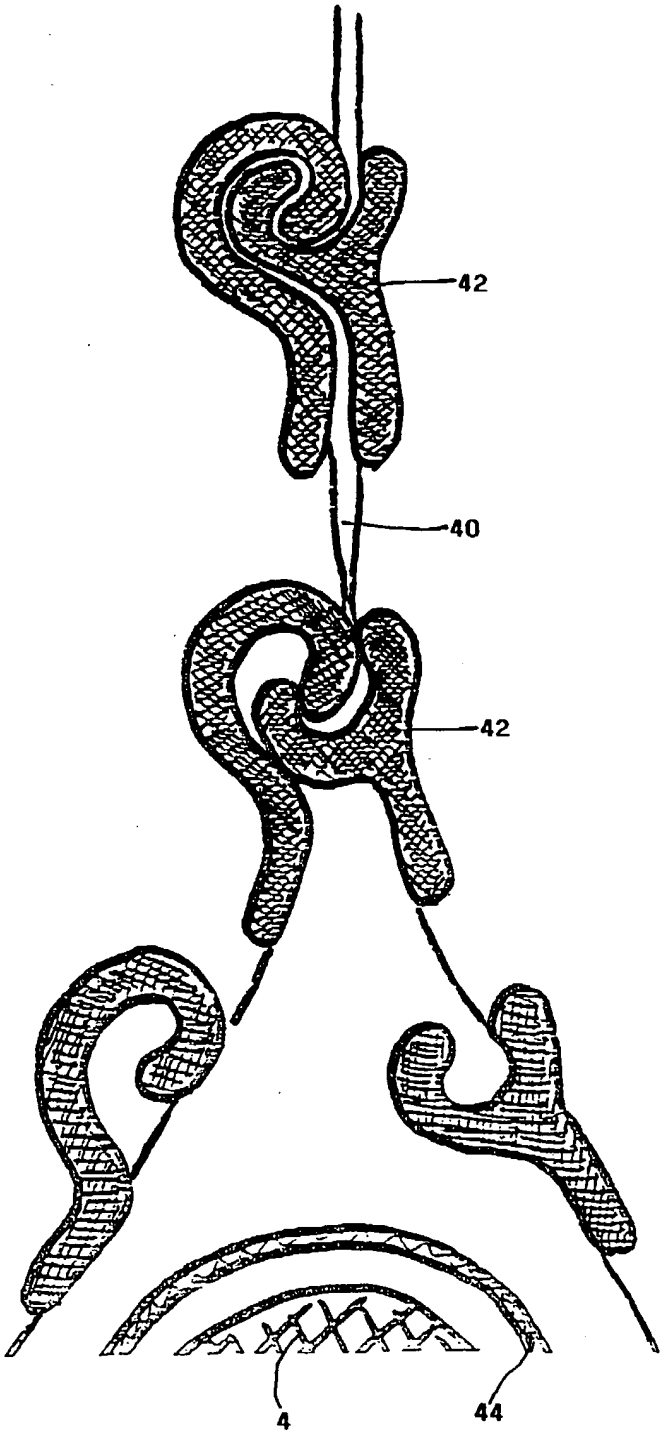

FIGURE 8

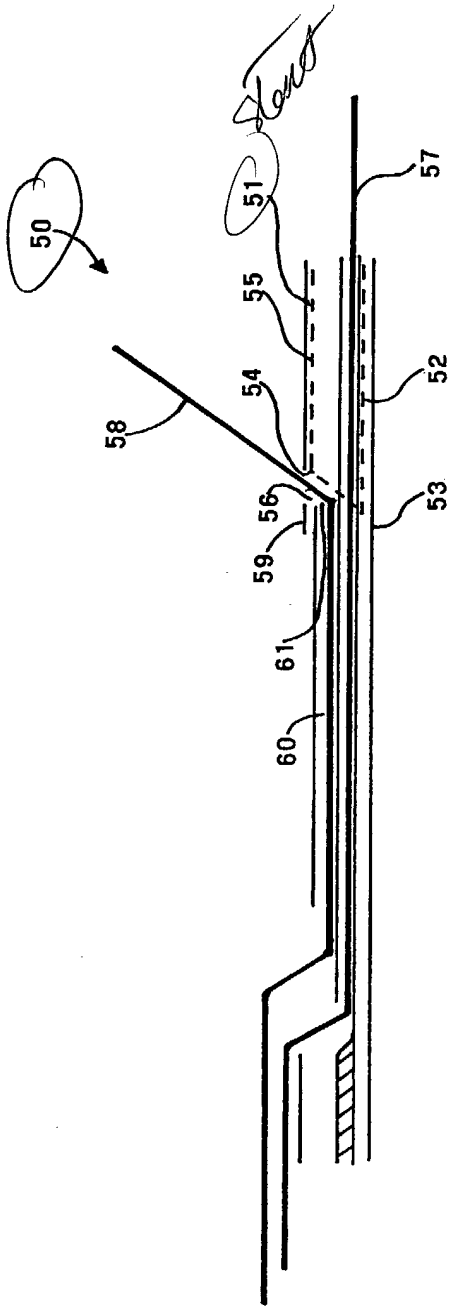

FIGURE 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NZ 99/00002

A. CLASSIFICATION OF SUBJECT MATTER

Int Cl[6]: A61F 2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC[6]: A61B 5/-, 17/-; A61F 1/-, 2/-; A61M 25/-, 29/-

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPAT & JAPIO with (catheter:, sleev:, capsul:, side:, lateral:, flank:, mid#, midway:, outlet:, aperture:, hole:, orifice:, opening:, window:, fenestrat:, port#)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97/45073 (BARD GALLWAY LIMITED) 4 December 1997 figures 6, 10, 12, pages 3 to 5	33,36
P,X	WO 98/36709 (SCIMED LIFE SYSTEMS INC) 27 August 1998 figures 9a, 9c	33,36

☐ Further documents are listed in the continuation of Box C

☒ See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 May 1999	24 MAY 1999
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No.: (02) 6285 3929	Authorized officer **ROSS BURDON** Telephone No.: (02) 6283 2605

INTERNATIONAL SEARCH REPORT

. ernational application No.
PCT/NZ 99/00002

Box I **Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: **45 to 48**
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

that these claims are not drafted in terms of the technical features of the invention.

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II **Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

as reasoned on an extra sheet.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims

2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NZ 99/00002

Box II (continued)

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1 to 32, and 37 to 44, are directed to a stent delivery sleeve for delivery of a self-expanding stent to a bifurcation wherein the stent delivery sleeve has a first outlet at the distal end and a second outlet in the side.It is considered that provision of a second outlet in the side of the stent delivery sleeve comprises a first "special technical feature".
2. Claim 33 is directed to a self-expanding stent with a lateral hole. It is considered that the lateral hole in the stent comprises a second "special technical feature".
3 Claim 36 is directed to a self-expanding stent with an angled proximal end. It is considered that the angled end of the stent comprises a third "special technical feature".

Since the abovementioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, a priori.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/NZ 99/00002

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
WO	97/45073	AU	27855/97	EP	844853	IT	970228
WO	98/36709	AU	66657/98				

END OF ANNEX